REMARKS

The March 2, 2005 Office Action required restriction from among:

Group I	claim(s) 1-4, 11-23, 37 and 50-52, drawn to a polypeptide comprising SEQ ID NO: 2;
Group II	claim(s) 1, 2, 5-7, 11-23, 37 and 50-52, drawn to a polypeptide comprising SEQ ID NO: 4;
Group III	claim(s) 1, 3, 8-10, 11-23, 37 and 50-52, drawn to a polypeptide comprising **SEQ** ID NO: 6;
Group IV	claim(s) 24-26, 29-31, 37, 48, 50-52 and 60, drawn to a purified nucleic acid molecule encoding SEQ ID NO: 2;
Group V	claim(s) 24, 25, 27, 29-31, 37, 48, 58-52 and 60, drawn to a purified nucleic acid molecule encoding SEQ ID NO: 4;
Group VI	claim(s) 24, 25, 28, 29-31, 37, 48, 50-52 and 60, drawn to a purified nucleic acid molecule encoding SEQ ID NO: 6;
Group VII	claim(s) 32-33, 37, 50, 52 and 61, drawn to a ligand that specifically binds to SEQ ID NO: 2;
Group VIII	claim(s) 32-33, 37, 50, 52 and 61, drawn to a ligand that specifically binds to SEQ ID NO: 4;
Group IX	claim(s) 32-33, 37, 50, 52 and 61, drawn to a ligand that specifically binds to SEQ ID NO: 6;
Group X	claim(s) 34-36, 37, 50 and 52, drawn to a compound that either increases or decreases the level of expression or the activity of SEQ ID NO: 2;
Group XI	claim(s) 34-36, 37, 50 and 52, drawn to a compound that either increases or decreases the level of expression or the activity of SEQ ID NO: 4;
Group XII	claim(s) 34-36, 37, 50 and 52, drawn to a compound that either increases or decreases the level of expression or the activity of SEQ ID NO: 6;
Group XIII	claim(s) 38-40, 46 and 56, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising binding a ligand to the polypeptide;
Group XIV	claim(s) 38-40, 46 and 56, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 4, or assessing the activity of a polypeptide comprising SEQ ID NO: 4, relative to a control, the method comprising binding a ligand to the polypeptide;
Group XV	claim(s) 38-40, 46 and 56, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 6, or assessing the activity of a polypeptide comprising SEQ ID

NO: 6, relative to a control, the method comprising binding a ligand to the polypeptide;

Group XVI claim(s) 41-42, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising binding a nucleic acid probe or primer to the gene encoding **SEQ** ID NO: 2;

Group XVII claim(s) 41-42, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 4, or assessing the activity of a polypeptide comprising SEQ ID NO: 4, relative to a control, the method comprising binding a nucleic acid probe or primer to the gene encoding SEQ ID NO: 4;

Group XVIII claim(s) 41-42, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 6, or assessing the activity of a polypeptide comprising SEQ ID NO: 6, relative to a control, the method comprising binding a nucleic acid probe or primer to the gene encoding SEQ ID NO: 6;

Group XIX claim(s) 43-45, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising detecting the presence of a mutation in the gene encoding SEQ ID NO: 2;

Group XX claim(s) 43-45, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising detecting the presence of a mutation in the gene encoding SEQ ID NO: 2;

Group XXI claim(s) 43-45, drawn to a method of diagnosing disease, comprising assessing the level of expression of a gene encoding SEQ ID NO: 2, or assessing the activity of a polypeptide comprising SEQ ID NO: 2, relative to a control, the method comprising detecting the presence of a mutation in the gene encoding SEQ ID NO: 2;

Group XXII claim(s) 47 and 49, drawn to a method of using SEQ ID NO: 2 as an adhesion molecule;

Group XXIII claim(s) 47 and 49, drawn to a method of using SEQ ID NO: 4 as an adhesion molecule;

Group XXIV claim(s) 47 and 49, drawn to a method of using SEQ ID NO: **6** as an adhesion molecule;

Group XXV claim(s) 53-55, drawn to a method of treating disease, comprising administering a polypeptide comprising **SEQ** ID NO: 2, or a pharmaceutical composition thereof;

Group XXVI claim(s) 53-55, drawn to a method sf treating disease, comprising administering a polypeptide comprising SEQ ID NO: 4, or a pharmaceutical composition thereof;

Group XXVII claim(s) 53-55, drawn to a method of treating disease, comprising a polypeptide comprising SEQ ID NO: 6, or a pharmaceutical composition thereof;

Group XXVIII claim(s) 53-55, drawn to a method of treating a disease, comprising administering a nucleic acid molecule that encodes SEQ ID NO: 2, or a pharmaceutical composition thereof;

Group XXIX claim(s) 53-55, drawn to a method of treating a disease, comprising administering a nucleic acid molecule that encodes SEQ ID NO: 4, or a pharmaceutical composition thereof;

Group XXX claim(s) 53-55, drawn to a method of treating a disease, comprising administering **a** nucleic acid molecule that encodes SEQ ID NO: 6, or a pharmaceutical composition thereof.

Group XXXI claim(s) 53-55, drawn to a method of treating a disease, comprising administering a ligand that specifically binds to SEQ ID NO: 2, or a pharmaceutical composition thereof;

Group XXXII claim(s) 53-55, drawn to a method of treating a disease, comprising administering a ligand that specifically binds to SEQ ID NO: 4, or a pharmaceutical composition thereof;

Group XXXIII claim(s) 53-55, drawn to a method of treating a disease, comprising administering a ligand that specifically binds to SEQ ID NO: 6, or a pharmaceutical composition thereof;

Group XXXIV claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to SEQ ID NO: 2;

Group XXXV claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to SEQ ID NO: 4;

Group XXXVI claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to SEQ ID NO: 6;

Group XXXVII claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to a nucleic acid molecule encoding SEQ ID NO: 2;

Group XXXVIII claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to a nucleic acid molecule encoding SEQ ID NO: 4;

Group XXXIX	claim(s) 57, drawn to a method of identifying a compound that is effective in treating or diagnosing disease, comprising selecting a compound that specifically binds to a nucleic acid molecule encoding SEQ ID NO: 6;
Group XL	claim(s) 58-59, drawn to a kit comprising a first container comprising a nucleic acid probe that hybridizes to a gene encoding SEQ ID NO: 2 and a second container comprising a primer for amplifying a gene that encodes SEQ ID NO: 2;
Group XLI	claim(s) 58-59, drawn to a kit comprising a first container comprising a nucleic acid probe that hybridizes to a gene encoding SEQ ID NO: 4 and a second container comprising a primer for amplifying a gene that encodes SEQ ID NO: **4;**
Group XLII	claim(s) 58-59, drawn to a kit comprising a first container comprising a nucleic acid probe that hybridizes to a gene encoding SEQ ID NO: 6 and a second container comprising a primer for amplifying a gene that encodes SEQ ID NO: 6;
Group XLIII	claim(s) 62, drawn to a transgenic or knock-out animal that expresses a higher, a lower or no level of SEQ ID NO: 2;
Group XLIV	claim(s) 62, drawn to a transgenic or knock-out animal that expresses a higher, a lower or no level of SEQ ID NO: 4;
Group XLV	claim(s) 62, drawn to a transgenic or knock-out animal that expresses a higher, a lower or no level of SEQ ID NO: 6;
Group XLVI	claim(s) 63, drawn to a method of screening for a compound to treat disease, comprising contacting a transgenic animal that expresses a higher, a lower or no level of SEQ ID NO: 2 with a candidate compound;
Group XLVII	claim(s) 63, drawn to a method of screening for a compound to treat disease, comprising contacting a transgenic animal that expresses a higher, a lower or no level of SEQ ID NO: 4 with a candidate compound; and,
Group XLVIII	claim(s) 63, drawn to a method of screening for a compound to treat disease, comprising contacting a transgenic animal that expresses a higher, a lower or no level of SEQ ID NO: 6 with a candidate compound.

Furthermore, the Office Action additionally required an election of species from each of the following:

a) each of the compounds listed in claim 36;

b) each of the diseases listed in claim 46;

c) each of the diseases listed in claim 52;

d) each of the abnormal expression levels listed in claim 62 - higher or lower or absent; and,

e) each of the abnormal expression levels listed in claim 63 - higher or lower or absent.

Applicants hereby elect, with traverse, the claims of Group III and inflammatory diseases. Applicants note that only one species has been elected herein in accordance with species (c) set forth in the Office Action on page 7 as the Group elected herein does not contain those claims referred to in the remaining species. Should the Examiner modify or withdrawn the restriction requirement, Applicants invite the Examiner to telephone the undersigned in order to obtain any additional required election of species.

The Office Action stated that "[t]he inventions listed as Groups I-XLVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features".

Applicants respectfully remind the Examiner that the present application was not filed under 35 U.S.C. §371. Rather, the present application was filed under 35 U.S.C. §111. While it is true that the present application claims priority to a international application, the filing of this application under 35 U.S.C. §111 instead of 35 U.S.C. §371 dictates that the present application be examined not under the PCT Rules, but in accordance with, *inter alia*, MPEP chapter 800. Accordingly, the restriction and election requirements set forth in the March 2, 2005 Office Action are improper and must be withdrawn as the present application was improperly examined under the PCT Rules.

Instead, as stated above, the application should have been examined in accordance with chapter 800 of the MPEP which lists two criteria for a proper restriction requirement. First, the invention must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application " [i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions." *Id.*

The Office Action makes no showing that the claims are independent or distinct inventions, and further there is no showing that search and examination of more than one of the forty-eight Groups delineated in the Office Action would place an undue burden on the Examiner. Indeed, although separated into forty-eight Groups, many of these claims encompass identical claims, with the distinctions delineated in the Office Action more properly being the subject of a species election than a restriction requirement. Further, Applicants were provided no indication as to the classification of the Groups presented, although review of the Groups results in the impression that there would likely be significant overlap between the Groups, thereby rendering the search and examination of the groups co-extensive. In addition, any burden placed on the Examiner by the search and examination of more than a single Group would be far less than the prejudice and burden placed on the Applicant should restriction be maintained such that the Applicant must file and prosecute over 45 separate applications in order to protect their invention.

At a minimum, it is respectfully asserted that the claims of Groups XXIV and XXVII should be rejoined with the claims of Group III. The claims of Group III are directed towards a polypeptide comprising SEQ ID NO: 6. The claims of Groups XXIV and XXVII are drawn to a method of using SEQ ID NO: 6 as an adhesion molecule, and to a method of treating disease, comprising administering a polypeptide comprising SEQ ID NO :6, or a pharmaceutical composition thereof, respectively.

Group III includes claim 1, which relates to a polypeptide which (i) has the amino acid sequence as recited in SEQ ID NO:2, SEQ ID NO:4, or SEQ ID NO:6; (ii) is a fragment thereof having activity as an adhesion molecule or having an antigenic determinant in common with the polypeptide of (i); or (iii) is a functional equivalent of (i) or (ii). Accordingly, claim 1 already considers that "fragments" of SEQ ID NO: 6 have activity as an adhesion molecule. Therefore, claim 1 and the claims of Group XXIV are interrelated. Similarly, the claims of Group XXVII are interrelated to the vaccine and pharmaceutical compositions of the claims of Group III.

Accordingly, the claims as originally filed represent a web of knowledge and continuity of effort that merits examination as a single invention, at the very least such that the claims of

Groups III, XXIV and XXVII are searched and examined together. Indeed, as the Office Action makes no showing that the Application meets the requirements for restriction the restriction requirement is improper and must be withdrawn, or at the very least, amended such that at a minimum, the claims of Groups III, XXIV, and XXVII (claims 1, 3, 8-10, 11-23, 37, 47, 49, 50-52 and 53-55) are searched and examined together.

Turning now to the election of species requirement, it is respectfully submitted that the application should have been examined in accordance with M.P.E.P. § 808.01(a), which states that "where there is no disclosure of relationship between species (*see* M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention" is required. In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

Instead of determining there is a disclosed relationship between the species, the Office Action instead states that election of species is required because the species are not art-recognized equivalents. It is respectfully submitted that whether or not the species are "art-recognized equivalents" is not the appropriate test. Rather, whether an election of species is proper turns on whether there is a disclosed relationship; in the instant case, the disclosed relationship between the species is one of functionality as the species from which restriction was required include: (i) compounds which serve the same function in modulating the level of expression or activity of the polypeptide of claim 1; (ii) diseases related to the level of expression or activity of the polypeptide of claim 1; and (iii) abnormal expression levels which in any instance signify a change in the expression or activity of the polypeptide of claim 1.

Furthermore, the species enumerated in the Office Action are sufficiently few in number that search and examination of the entire species would not place an undue burden on the Examiner. Therefore, reconsideration and withdrawal of the election of species requirement are requested.

In view of the remarks herein, enforcing the present restriction and election of species requirements would result in inefficiencies and unnecessary expenditures by the Applicants and

the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially in view of the requisite showing that a serious burden has not been met, and in view of the improper examination of the application under the PCT Rules. Indeed, the search and examination of each Group would likely be co-extensive and, in any event, would involve such interrelated art that search and examination of the entire application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction and election species.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal, or at least modification, of the election of species and restriction requirements, such that, at the least, the claims of Groups XXIV and XXVII are searched and examined with the claims of Group III.

CONCLUSION

Reconsideration and withdrawal of the restriction requirement and election of species and an early and favorable examination on the merits is respectfully requested in view of the remarks herein.

Respectfully submitted,

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